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REMARKS

Receipt of the Office Action mailed January 27, 2010, in the above-identified patent application is respectfully acknowledged. Claims 1-20 remain in the application. Claims 1-3 and 20 have been amended. Reconsideration of the claims, as amended, in view of the following Remarks is respectfully requested.

I. The Claim Rejections Under 35 U.S.C. § 112, Second Paragraph

Claims 2 and 3 have been amended to overcome the rejection of claims 2-4 raised under section 35 U.S.C. 112, second paragraph, by deleting the words “preferably at the exit aperture”. Since claim 4 is dependent on claim 3, it is respectfully submitted that this rejection is now obviated for claims 2-4.

II. The Claim Rejections Under 35 U.S.C. § 102

Turning then to the rejections to claim 1 under section 35 U.S.C. 102(b), claim 1 has been amended to clarify the subtle but important physical differences between the present invention and the devices of the prior art. The surgical device of the present invention is designed to allow hand assisted laparoscopic surgery to be performed in the absence of direct insufflation gas, unlike the devices of Leyva (US5,522,791) and Beane et al. (US6,142,936), both of which have been cited against claim 1. Thus while there are physical similarities between the device of the present invention and the prior art devices of Leyva and Beane et al., the subtle physical differences alter significantly the functionality of the device of the present invention. The devices of Leyva and Beane et al are, in use, secured about a surgical incision, to define an access port for a surgeon’s hand, which seals against the surgeons arm in order to prevent the escape of insufflation gas, which must be continuously pumped directly into the surgical cavity in order to distend same. The device of the present invention avoids this requirement, as set out on page 7, lines 22-25, and is thus a significant improvement over the prior art.

The devices of both Leyva and Beane et al. are described as being adapted to retract the edges of a surgical incision, in order to facilitate ease of access to a surgical cavity, which must however be inflated using separate insufflation gas. See Leyva ‘791 at column 4, lines 50-59, and column 6, lines 19-43, and Beane et al. ‘936 column 6, lines 50-53.

Turning firstly to Leyva, the device disclosed therein is a hand access port to be secured about a surgical incision, to provide access to a surgical cavity and to prevent the escape

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of insufflation gas from the cavity. Thus the device of Leyva is intended for use with insufflation gas. Although the hand access port of Leyva includes a distensible member in the form of an inflatable member (24), this member is located within the annulus (12), and is intended to seal the annulus against the surgical incision to prevent the escape of insufflation gas from the surgical cavity. The inflatable member is not intended, nor located to be suitable for, direct distension of the surgical cavity. It is, therefore, respectfully submitted that claim 1 of the present application is novel by virtue of the positioning of the distensible member to be locatable within the cavity, in addition to being distensible to an extent that the cavity can be enlarged to permit hand assisted surgery to be performed therein.

Leyva does not suggest or imply the use of a distensible member to enlarge the cavity, and it is therefore respectfully submitted that amended claim 1 is both novel and inventive and not obvious over the disclosure of Leyva, whether alone or in combination with Beane et al.

Turning then to Beane et al., the device disclosed includes a pair of inflatable collars 68, 69 which are located, in use, externally of the surgical cavity about the surgical incision, while a solid ring 64 is located against the inner edge of the incision. See Figs. 2C, 2D and 2E of Beane et al. The collars 68, 69, upon inflation, effect retraction of the incision in order to allow access therethrough. As detailed at column 6, line 52, once the wound has been retracted, it is then necessary to inflate the surgical cavity using insufflation gas. The function of the inflatable collars 68, 69 is thus solely to effect retraction of the edges of the surgical incision, and not in any way to distend the surgical cavity itself to enable surgery to be performed therein. The device of the present invention avoids the requirement for the use of a separate insufflation gas, by positioning the distensible member such as to be located, in use, within the surgical cavity. Claim 1 has therefore been amended to clarify this positioning of the distensible member. Support for this amendment can be found at page 7, lines 15 – 16.

In addition, the distensible member is inflatable to such a degree that it distends the surgical cavity, thereby allowing hand assisted surgery to be performed within the cavity in the absence of any insufflation gas. Claims 1 and 20 have been amended to introduce this physical requirement. Support for this amendment can be found at page 7, lines 17 – 19. While the Applicant acknowledges that the limitation introduced into Claim 1 for the distensible member to be “sufficiently distensible to distend the cavity an amount which will allow hand

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assisted surgery to be performed” is an attempt to define a physical feature of the invention by a result to be achieved, it is respectfully submitted that this feature cannot otherwise be defined more precisely without unduly restricting the scope of the claims. In particular, the distensible member may vary considerably in dimensions, depending on the type of surgery being performed, and may for a given size be inflated to various volumes, even during a single surgical procedure (see page 9, lines 14 – 20). Thus, as well as being located internally of the cavity during use, the distensible member must be inflatable to a volume significantly greater than the inflatable collars 68, 69 of Beane et al., which as mentioned above are in no way intended to effect inflation of the cavity. It is, therefore, respectfully submitted that amended claim 1 is novel by virtue of the above limitations now introduced.

Furthermore, as this concept of distending a surgical cavity in the absence of an insufflation gas is neither suggested nor implied by the disclosure of Beane et al., it is also submitted that amended Claim 1 is inventive and not obvious over Beane et al., whether alone or in combination with Leyva.

It is, therefore, respectfully submitted that claim 1 as amended is both novel and inventive over the cited prior art.

III. The Claim Rejection Under 35 U.S.C. § 103(a)

The Examiner has also rejected original claim 14 under 35 U.S.C. § 103(a) as being unpatentable over Leyva ‘791 or Beane et al. ‘936 in view of Leahy et al. US 5,640,977. It is respectfully submitted that, because claim 14 is dependent from claim 1, the above discussed amendments to claim 1 also overcome this rejection of claim 14.

More specifically, the Examiner has alleged that Leahy discloses a surgical sleeve provided with lubricant and that it would have been obvious at the time of the present invention to one of ordinary skill to modify the device of either Leyva or Beane et al. to include the sleeve of either reference being provided with lubricant in view of Leahy et al. While Leahy et al. ‘977 does disclose the inclusion of a lubricant, the entire device of Leahy et al. is significantly different from that of the present invention just as was the case with Leyva ‘791 and Beane et al. ‘936. In this regard, Leahy et al. discloses the use of a wound protector 12 including O-rings 14,16 that are placed over the internal edge of a wound such that tube 13 is positioned over the edges of the wound. As explained at column 5, lines 35-52, and column 6, lines 57-64 insufflation gas is used during the procedure to expand the abdominal cavity. There is no

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disclosure, teaching or suggestion for including a distensible member positioned on a sleeve to be located within the cavity and being sufficiently distensible to distend the cavity in an amount which will allow hand assisted surgery to be performed within the cavity as is now set forth in amended claim 1. Therefore, even though Leahy et al. '977 discloses the use of a lubricant, it does not disclose, teach or suggest a surgical device as now set forth in amended claim 1 or amended claim 14.

Moreover, there is no basis to combine Leahy et al. with either Leyva or Beane et al. to provide the surgical device of amended claims 1 or 14. Even if Leahy et al. '977 is combined with Leyva and/or Beane et al., the references taken either alone or in combination fail to disclose a surgical device as now set forth in amended claims 1 and 14. Accordingly, it is respectfully submitted that claim 14 is also patentable over these three references taken alone or in any combination in view of the amendments to claim 1.

IV. Summary

Accordingly, in view of the above amendments and Remarks, it is respectfully submitted that claims 1-20, including claims 1-3 and 20, as amended, are patentable and now in condition for allowance. A notice to that effect is earnestly and respectfully requested.

Respectfully submitted,

PATRICK LEAHY

By: Van Dyke, Gardner, Linn & Burkhardt, LLP

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Date

Donald S. Gardner
Donald S. Gardner
Reg. No. 25 975
Van Dyke, Gardner, Linn & Burkhardt, LLP
2851 Charlevoix Drive, S.E.
P.O. Box 888695
Grand Rapids, MI 49588-8695
(616) 975-5502

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Enclosure